

REMARKS

Claims 1-12 and 14-32 are pending in the application.

Claim 3 is objected to, but would be allowable if rewritten in independent form.

Claims 1, 2, 4, 6, 10-12 and 14-32 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Pub. No. 2003/0074002 A1 to West, Jr. ('West') in view of U.S. Pat. No. 6,019,762 to Cole ('Cole'). The applicants respectfully traverse the Examiner's rejection for the following reasons.

In the claims, the applicants claim various aspects of a fracture fixation pin that has structure permitting maximum pin concealment within the bone while also permitting extraction if necessary (longitudinal grooves about the outer circumference of a threaded portion), and increased bone purchase adjacent the location of pin insertion (threads of an increased diameter, but common pitch, relative to more distal threads) thus enhancing overall pin stabilization.

The Examiner states that West discloses a fracture pin having all the claimed features except for the second portion being provided with a plurality of longitudinal grooves about an outer circumference of said second portion, and that Cole teaches such grooves for engagement by a driving tool to drive the fastener into surrounding bone. Thus, the Examiner concludes it would have been obvious to replace the bore of West

with the grooves of Cole in order to use a corresponding drive tool and thus arrive at the claimed invention.

With respect to claim 1, this argument has several problems which relate directly to the last clause of claim 1:

a plurality of longitudinal grooves extending crosswise through at least one of said second threads, said grooves being located adjacent said shaft portion and spaced-apart about an outer circumference of said second portion.

First, while Cole may disclose some 'grooves', such grooves are not on a pin. They are on a separate ferrule head 30 which may be later coupled to a fixation pin 10 by crimping after each is separately inserted into bone. (Col. 6, lines 10-35; Fig. 1) Furthermore, the 'grooves' in Cole are not the claimed longitudinal grooves, but are slots 40 akin to slots on a top of a screw. These slots are provided only in an upper tapered portion of the head 30. As clearly seen in Fig. 2, such slots 40 open to the internal channel 46, but do not extend to the outer circumference of the ferrule. (See circle defining the outer circumference identified by reference numeral 36 in Fig. 2 and note that the slots 40 terminate radially within this circle and thus do not extend to the outer circumference.) Therefore, the slots are not "about an outer circumference of said second portion".

Second, both West and Cole fail to teach any "longitudinal grooves extending crosswise through at least one of said second threads." No grooves in the devices of

either of the references interrupts the threads. Clearly, as seen in Fig. 1 of Cole, slots 40 do not extend anywhere close to external threads 32. In addition, the drive socket 24 in the interference screw of West is internal, while the threads are external. Thus, no portion of the drive socket extends cross-wise through the external threads thereof.

Third, the slots 40 of Cole are not provided on a *solid* portion of the device, as required by the language of claim 1. The slots 40 are provided on a "ferrule" head portion 30 which is separate from elongated shaft 10. The ferrule head 30, as all ferrules, is *hollow*, not solid. The head portion 30 is only coupled to the shaft by crimping after separate insertion of both the shaft 10 and head 30 into the bone. See again col. 6, lines 10-35. Similarly, West teaches a hollow screw.

Fourth, contrary to the Examiner statement, West fails to even disclose a *fracture* pin; i.e., a pin structurally designed to attach fractured pieces of bone together. West teaches an interference screw for affixing soft tissue grafts to bone during anterior cruciate ligament (ACL) reconstruction. As bone fracture fixation pins and soft tissue-to-bone attachment devices are intended for different purposes they are non-analogous art, and there would not be incentive to combine the references.

Furthermore, claim 16, as amended, requires first and second threaded portions, with threads along "substantially an entirety" of the second portion, and the second portion also defining "a plurality of longitudinal spaced apart negative spaces about an

outer circumference." For reasons provided above with respect to claim 1, claim 16 is not shown or suggested by the cited art.

Claim 18, as amended, states that the "longitudinal grooves [are] spaced-apart about an *outermost* circumference of said second portion and [also extend] crosswise through at least one of said second threads." For the reasons advanced above with respect to claim 1, this is not shown or suggested by the cited art.

Claim 21 requires a one-piece pin having non-hollow first and second threaded portions. The entirety of the West screw is hollow. The system of Cole is two-piece, with a hollow partially threaded ferrule head. While the "one-piece" language has been added for clarity, such is already inherent by definition of a pin, which is a unitary construct. In addition, the claim requires "a plurality of longitudinal grooves spaced-apart about an outer circumference of said second portion." For the reasons provided above, neither reference teaches or suggests this arrangement.

Claim 23 requires that a portion of a threaded portion of the pin includes "a plurality of longitudinal grooves extending parallel to a longitudinal axis of said pin and located adjacent said shaft portion and spaced-apart about an outermost circumference of said threaded portion." For the reasons advanced above, it is submitted the art of record fails to teach or suggest these limitations.

Claim 31 requires a pin having a first portion provided with threads and a shaft portion, said first portion including a tip end and an opposite end, said opposite end including a plurality of longitudinal grooves extending crosswise through at least one of said threads and located adjacent said shaft portion and spaced-apart about an outer circumference of said first portion. For the reasons advanced above, it is submitted the art of record fails to teach or suggest these limitations.

For the foregoing reasons, claims 1, 16, 18, 21, 23, 31 and all claims dependent thereon are allowable over West in view of Cole.

Claim 5 stands rejected under 35 U.S.C. § 103(a) as obvious over West in view of Cole. The Examiner argues that the claimed dimensions are merely an obvious matter of design choice and within the level of ordinary skill in the art. The applicants respectfully traverse the rejection for the following reasons. First, for the reasons advanced with respect to claim 1, claim 5 is allowable. Second, the West device is not a fracture pin, but rather a screw for attaching soft tissue to bone for ACL reconstruction. As the West screw is intended to be used for a completely different purpose, it is not merely a matter of design choice to provide the claimed dimensions. The claimed dimensions provide functionality for bone to bone repair, while West teaches only with respect to soft tissue to bone repair. Therefore, claim 5 is not obvious over West in view of Cole.

Claims 7-9 stand rejected under 35 U.S.C. § 103(a) as obvious over West in view of Cole, as applied to claim 1, and further in view of U.S. Pat. No. 6,454,772 to Jackson.

The applicants respectfully traverse the Examiner's rejection for the following reasons.

The Examiner correctly notes that West fails to teach a frangible portion between the second portion and the shaft. However, the Examiner states that "West discloses that the device may be severed and part of the device removed." The Examiner identifies Jackson as teaching a frangible portion that breaks away after a preselected torque is applied. The combination of this teaching of Jackson with West is problematic for several reasons.

First, the devices of West and Jackson are non-analogous art. Under the test set forth in In re Wood, 202 USPQ 171 (CCPA 1979), art is analogous if it is (1) from the same field of endeavor or if it is (2) reasonably pertinent to the particular problem with which the inventor is involved. This test was interpreted by the Federal Circuit in In re Clay, 23 USPQ2d 1058 (Fed. Cir. 1992), where the Federal Circuit noted that even where two references were related to the use of gel in improving the flow of petroleum fluids, they were not from the same field of endeavor and the reference was not reasonably pertinent to the particular problem with which Clay was involved.

In the present case, the screw of West (which attaches soft tissue to bone) and the set screw of Jackson (which couples two metal implants together) are clearly not in the same field of endeavor. In addition, the Jackson set screw is not reasonably pertinent to the problem of the invention. The problem of the invention is that when providing a fixation pin having a non-threaded shaft portion which is frangibly connected to a threaded portion of the pin, how to withdraw the screw *after* the pin has been inserted

*until the threaded portion is flush with or slightly recessed into the bone and the non-threaded shaft portion is removed from the pin.* See Spec. at page 4, line 15 through page 5, line 22; page 11, line 14, page 12, line 8.

In addition, the Jackson set screw includes machine threads which are specifically intended for interconnecting two implants, while the West screw includes self-tapping threads intended for insertion into soft tissue and bone.

Therefore, the Jackson set screw is not from the same field of endeavor and does not seek to solve the same problem as the invention. Thus, Jackson is not analogous art.

Moreover, even if the references were analogous art, there would be no appropriate suggestion to pull elements of one and combine such with elements of the other, absent a hindsight reconstruction based upon applicant's disclosure. "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." In re Keller, 202 U.S.P.Q. 500 (C.C.P.A. 1979). Further, "[i]t is impermissible to first ascertain factually what the [inventor] did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct [inventor's] invention from such prior art." Panduit Corp. v. Dennison Mfg. Co., 227 U.S.P.Q. 337, 343 (Fed. Cir. 1985)(citing In re Shuman, 361 F.2d 1008, 1012, 150 U.S.P.Q. 54, 57 (C.C.P.A. 1966).

Third, in the claimed fixation pin and in the West screw, it would not be desirable to have *any* breakage due to torque. In such devices that are insertable directly into bone, the devices generally must seat at a desired depth, *regardless of the torque*. However, in the machine screw of Jackson, the clamping force to join two implant elements (as indicated by the torque force) is what is desired to be controlled. There is no suggestion to apply a teaching with respect to torque forces to implants intended to directly seat within the bone at a desired depth. Specifically, it is noted that the shaft portion of the claimed screw is intended to remain connected to the fixation pin until the pin is fully seated, and only then is it *frangibly disengaged by bending or cutting, not by torque*:

The pin 10 is inserted until the intersection of the second portion 16 and the shaft portion 26 lies flush with, or more preferably slightly recessed relative to, the surface of the distal fragment. The shaft of the pin is then removed from the pin, e.g., by bending or cutting. (Spec. at page 10, line 25 – page 11, line 4)

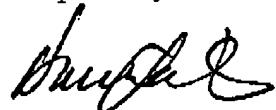
Furthermore, for the reasons advanced with respect to claim 1, claims 7-9 are allowable.

For the foregoing reasons, claims 7-9 are allowable over the cited art.

It is believed that the above places the claims in condition for allowance. Furthermore, any amendments made are intended for purposes of clarity, and are not believed to raise any new issues for consideration.

In light of all of the above, it is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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